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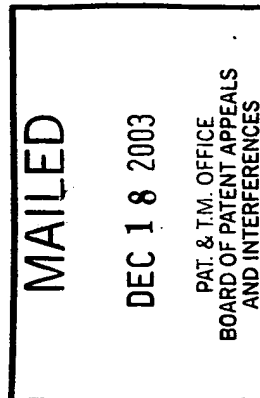
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
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Paper No: 15
Appeal No: 2004-0445
Appellant: DOYLE, MATTHEW JOSEPH
Application: 09/607,240

**Board of Patent Appeals and Interferences
Docketing Notice**

Application 09/607,240 was received from the Technology Center at the Board on December 9, 2003 and has been assigned Appeal No: 2004-0445.



A review of the file indicates that the following documents have been filed by appellant:

Appeal Brief filed on: March 21, 2003
Reply Brief filed on: None
Request for Hearing filed on: None

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

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By order of the Board of Patent Appeals and Interferences

cetylpyridinium chloride (CPC); tetradecylpyridinium chloride (TPC); N-tetradecyl-4-ethylpyridinium chloride (TDEPC); octenidine; delmopinol; octapinol; nisin; zinc ion agent; copper ion agent; essential oils; furanones; bacteriocins; salts thereof; and mixtures thereof.

8. A method for promoting whole body health in human and other animal subjects, comprising topically administering to said subjects' oral cavity a composition comprising
 - a. a safe and effective amount of an antimicrobial agent selected from the group consisting of stannous ion agent, triclosan, triclosan monophosphate, chlorohexidine, domiphen bromide; cetylpyridinium chloride (CPC), zinc ion agent, copper ion agent, essential oils, and mixtures thereof;
 - b. a safe and effective amount of an additional therapeutic agent; and
 - c. a pharmaceutically-acceptable topical, oral carrier.

The examiner relies upon the following reference:

Singer et al. (Singer)	5,364,616	Nov. 15, 1994
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Claims 5-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Singer. After careful review of the record and consideration of the issues before us, we affirm.

BACKGROUND

According to the specification,

The present invention relates to promoting and enhancing whole body health or overall systemic health in humans and other animals, by using topical oral compositions comprising one or a mixture of antimicrobial agents, which effectively control bacterial-mediated diseases and conditions present in the oral cavity and inhibit spread of oral pathogenic bacteria, associated bacterial toxins and endotoxins and inflammatory cytokines and mediators prompted by these oral pathogens. More particularly, the present invention relates to methods of using the present topical oral compositions to reduce the risk in development of cardiovascular disease, stroke, atherosclerosis, diabetes, severe respiratory

infections, premature births and low birth weight, post-partum dysfunction in neurologic and developmental functions, and associated increased risk of mortality by treating and preventing diseases and conditions of the oral cavity.

Id. at 1.

The specification notes that "periodontal disease (gum disease) may be a far more serious threat to overall systemic health than previously realized." Id. As taught by the specification, "microorganisms contribute to both the initiation and progress of periodontal disease," and that "in order to prevent or treat periodontal disease, these microorganisms must be suppressed by some means other than simple mechanical scrubbing." Id. at 5. Thus, a great deal of research has focused on the development of methods of treating periodontal disease through the suppression of those microorganisms. See id.

DISCUSSION

Claims 5-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Singer.

As an initial matter, appellants state that there are two separate groups of claims, with group I consisting of claims 5, 6 and 8, and group II consisting of claims 7 and 9. Appellants, have not, however, separately argued the patentability of the group II claims, so we focus our analysis on the broadest claim, claim 5. See 37 CFR 1.192(c)(7); see also In re Dance, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998) (noting that dependent

claims not argued separately on the merits rise or fall with the independent claim to which they relate).

Due to its brevity, the entire rejection is set forth below.

[Singer] teaches a method for treatment and prevention of the oral cavity diseases of gingivitis or periodontis comprising the topical administration of the oral cavity of a composition comprising an antimicrobial anti-plaque agent (including numerous agents instantly recited in claims 1-2 [sic] and 8), and a histamine-2 receptor antagonist compound (including many agents instantly recited in claim 4 [sic]) and a pharmaceutically acceptable oral carrier [Singer] further teaches that said oral carrier contains components that are suitable for administration to the oral cavity of a human or lower animal It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex parte Novitski, 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304).

Therefore, the referenced teachings anticipate the claimed invention.

Examiner's Answer, pages 3-4 (citations omitted).

We recognize that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). Appellants, however, do not dispute that

Singer teaches a method comprising topically administering to a subjects' oral cavity a composition comprising an antimicrobial agent and a pharmaceutically acceptable oral carrier. Rather, appellants argue that "Singer [] does not disclose the 'new use' of the present method, i.e., promoting whole body or systemic health." Appeal Brief, page 4. We disagree, however, that the purported new use of promoting whole body or systemic health constitutes a patentable difference, and we affirm the rejection.

First, we agree with the examiner that the recitation of "[a] method for promoting whole body health in human and other animal subjects" is an intended use, and not a patentable limitation.

The examiner cited Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc., 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001) to support the proposition that promoting whole body health was intended use, and not a patentable limitation. Appellants argue that the examiner overstated the holding in Bristol-Myers Squibb, asserting that "the 'use' in Bristol, i.e., 'treating cancer by administering paclitaxel' is the 'same use' as disclosed in the prior art." Appeal Brief, page 5. Appellants contend that "[i]n contrast to Bristol, the claims of the present invention relate to a new and different use or purpose, i.e., promoting whole body health." Id. at 6.

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the

balance of the claim. . . . If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of the limitations, and the preamble offers no distinct definition of the claimed invention's limitations, but merely states, for example, the purpose of the intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.2d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

In the instant case, in order to perform the claimed method, all one need do is topically apply to a subject's oral cavity a composition comprising a safe and effective amount of an antimicrobial agent and a pharmaceutically acceptable oral carrier. Appellants do not argue that that method is not taught by Singer, but argue that the claims of the present invention relate to a new and different use or purpose, i.e., promoting whole body health, which is not recognized by Singer. The body of claim 5, however, sets forth a complete method, and the recitation in the preamble of "[a] method for promoting whole body health" does not affect or change how the method is performed. Thus, we find that the body of the claim fully and intrinsically sets forth the complete invention, including all of the limitations, and the preamble offers no distinct definition of the claimed invention's limitations. The recitation of "[a] method for promoting whole body health" is therefore merely a statement of intended use and not a patentable limitation.

Moreover, even if we were to find that the recitation of “[a] method for promoting whole body health in human and other animal subjects” in the preamble is a limitation, we again agree with the examiner that it is a result that is inherently achieved by the method of Singer, and is thus anticipated by that reference.

Appellants assert that in the other cases cited by the examiner in the rejection, “the claimed method was directed to the same use and not a new use or purpose.” Appeal Brief, page 6. For example, appellants note that in In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1575 (Fed. Cir. 1990) the claimed use was to inhibit the visible growth of fungi on refrigerated fruits and vegetables was generically encompassed by the prior art process of storing fresh and leafy vegetables in a modified atmosphere. See Appeal Brief, page 6. Appellants assert, however, that “[i]n the present case, promoting systemic or whole body health can not be considered to be generically encompassed by the treatment of nonsystemic conditions of dental plaque, gingivitis and periodontitis.” Id.

Appellants argue further that the examiner erred in finding that the present method claims are not patentable because the result of whole body health benefits is inherent in the method taught by the prior art. See id. at 7. Appellants assert that Bristol Myers Squibb supports patentability of the instant claims, as the court stated that “new uses of known processes may be patentable.” Appeal Brief, page 5, quoting Bristol Myers Squibb, 246 F.3d at 1376, 58 USPQ2d at 1514. Moreover, citing In re Marshall, 578 F.2d 301, 198

USPQ 344 (CCPA 1978), and In re Shetty, 566 F.2d 81, 195 USPQ 753 (CCPA 1977), appellants argue that “claims drawn to a method for using either an old or ‘obvious’ composition, wherein the method has unobvious or beneficial or useful effects, have been found patentable even though the composition itself could not be patented.” Appeal Brief, page 7. Appellants conclude:

As in the Shetty and Marshall cases, the Examiner has not provided any evidence whatsoever to establish that one of ordinary skill in the art would appreciate or recognize the new use of the present claimed method, i.e., promoting systemic or whole body health. There is no disclosure or even a remote suggestion in Singer [] that a method involving topical administration of a composition containing the recited antimicrobials as opposed to systemic administration would be useful in promoting systemic health. In fact, all of Singer’s disclosure relate to the use of H2 antagonist compounds to treat periodontitis and gingivitis. The presence of an antimicrobial antiplaque agent is optional. Accordingly, the rejection of the claims under § 102(b) over Singer [] cannot stand.

Id. 9.

As noted by the examiner, the Court of Appeals for the Federal Circuit, our reviewing court, stated that “[i]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.” In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1575, 1936 (Fed. Cir. 1990) (emphasis in original); see also Bristol-Myers Squibb Co. 246 F.3d at 1376, 58 USPQ2d at 1514 (“Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.”). As to inherency, the court has noted that “[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes,

the claimed limitations, it anticipates.” Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.2d 1362, 1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted). Moreover, “[w]here . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article’s authors did not appreciate the results.” Mehl/Biophile Int’l Corp., 192 F.2d at 1366, 52 USPQ2d at 1307.

In the instant case, the only actual method step required by claim 5 is topically applying an antimicrobial composition to a subject's oral cavity. That is the same process step taught by Singer. Although Singer did not appreciate the result of imparting whole body health, it is a necessary consequence of applying the antimicrobial composition to the oral cavity. Thus, the result is inherent in the process of Singer, and as Singer teaches all of the limitations of claim 5, the examiner properly applied it as an anticipatory reference.

Admittedly, as noted by appellants, the court in Woodruff recognized that the claimed use was not directed to a different purpose, as the generic method of the prior art encompassed the benefit disclosed by Woodruff. See Woodruff, 919 F.2d at 1577-78, 16 USPQ2d at 1935-36. We do not find, however, that that should lead to a different conclusion in the instant case. The purpose of applying the antimicrobial to the oral cavity in Singer and in the present invention is the same, i.e., killing bacteria (microbes) in the oral cavity. Appellants have merely recognized a benefit that was not explicitly recognized by Singer, i.e., the promotion of whole body health.

Furthermore, it is the opinion of the panel that the courts discussion in Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.2d 801, 62 USPQ2d 1781, (Fed. Cir. 2002) is instructive. In discussing whether the preamble may constitute a patentable limitation, as well as the principle of inherency, the court gave the following hypothetical:

Inventor A invents a shoe polish for shining shoes (which, for the sake of example, is novel, useful, and nonobvious). Inventor A receives a patent having composition claims for shoe polish. Indeed, the preamble of these hypothetical claims recites "a composition for polishing shoes." Clearly, Inventor B could not later secure a patent with composition claims on the same composition because it would not be novel. Likewise, Inventor B could not secure claims on the method of using the composition for shining shoes because the use is not a "new use" of the composition but, rather, the same use shining shoes.

Suppose Inventor B discovers that the polish also repels water when rubbed onto shoes. Inventor B could not likely claim a method of using the polish to repel water on shoes because repelling water is inherent in the normal use of the polish to shine shoes. In other words, Inventor B has not invented a "new" use by rubbing polish on shoes to repel water. Upon discovering, however, that the polish composition grows hair when rubbed on bare human skin, Inventor B can likely obtain method claims directed to the new use of the composition to grow hair.

Catalina Marketing Int'l, Inc., 289 F.3d at 809-10, 62 USPQ2d at 1786 (citations and quotations omitted).

The instant case is more like discovering that shoe polish also repels water rather than discovering that shoe polish grows hair when rubbed on human skin. With respect to the hypothetical of discovering that shoe polish when rubbed on shoes repels water, the method is the same as taught by the prior art, rubbing shoe polish on shoes, and achieves a result that was inherent in,

although not recognized by the prior art. With respect to a method of growing hair, there is a step that is not taught nor suggested by the prior art, rubbing shoe polish on skin. The instant claims require no more than is taught by the prior art, that is, applying an antimicrobial composition to the oral cavity. The recitation of "promoting whole body health" in the preamble of claim 5 does not add any additional method steps, such as rubbing shoe polish on skin when the prior art teaches rubbing it on shoes, that is not taught or suggested by the prior art.

Finally, with respect to the appellants' arguments that other issued patents support the patentability of the instant claims, see Appeal Brief, pages 9-10, the patentability of different claims in separate applications are decided on their own facts, and we will not engage in idle speculation as to why the claims were found to be allowable in the patents cited by appellants.

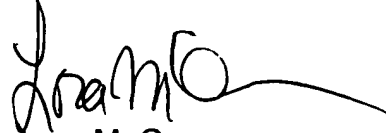
AFFIRMED


William F. Smith

Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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